Interim Clearance Strategy for Environments Contaminated with *Bacillus anthracis*

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14. ABSTRACT
If a Bacillus anthracis incident occurs in the United States or within its territories, the public health and environmental communities must work collaboratively during the response to most effectively address the risks posed by the incident. The ultimate goal is to effectively and efficiently remediate the environment so that the local or state public health officials or private building owners can make follow-on decisions. The remediation phase of a response includes characterization, decontamination, and clearance, as defined in the White House Office of Science and Technology Policy (OSTP) draft document, Planning Guidance for Recovery Following Biological Incidents. To that end, a group of experts from Center for Disease Control (CDC) and EPA met to discuss the current state-of-the-science on risk assessment, sampling strategies, decontamination technologies, and operational logistics as it relates to the development of a clearance strategy. This document was developed as a result of this meeting and is a living document that will be updated as the state-of-the-science changes and is complementary to the broader overarching OSTP document previously mentioned.

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Disclaimer:

The strategy set forth here is intended as an interim guide for public health and environmental Federal responders. It represents knowledge from best practices and available science. This strategy will be reviewed biennially as new information becomes available. The incident command/unified command (IC/UC) is ultimately responsible for developing site- and incident- specific clearance strategies.

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The Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) have developed this interim clearance strategy to aid Incident Command/Unified Command (IC/UC) in clearing a building or an outdoor environment after an incident involving contamination with *Bacillus anthracis* (*B. anthracis*). The strategy is based on the best available science and most practical approach, and is intended for use by public health and environmental Federal responders supporting the IC/UC responding to a *B. anthracis* incident.

For the purpose of this document, the clearance strategy is defined as the approach used to meet a pre-defined clearance goal and the associated process to determine that the goal has been achieved. Developing and implementing a clearance strategy for the purpose of remediating indoor and outdoor areas after contamination is a critical environmental and public health need. Ultimately, the clearance decision generally rests with the local or state public health officials or property owner(s).

Purpose:

If a *B. anthracis* incident occurs in the United States or within its territories, the public health and environmental response communities must work collaboratively during the response to most effectively address the risks posed by the incident. The ultimate goal is to effectively and efficiently remediate the environment so that the local or state public health officials or private building owners can make follow-on decisions. The remediation phase of a response includes characterization, decontamination, and clearance as defined in the Office of Science and Technology Policy (OSTP) draft document, *Planning Guidance for Recovery Following Biological Incidents*. (OSTP, 2009)

To that end, a group of experts from CDC and EPA met to discuss the current state-of-the-science on risk assessment, sampling strategies, decontamination technologies, and operational logistics as they relate to the development of a clearance strategy. The *Interim Clearance Strategy for Environments Contaminated with Bacillus anthracis* was developed as a result of this meeting and is a living document that will be updated as the state-of-the-science changes. This strategy document is complementary to the broader overarching draft OSTP document previously mentioned. The OSTP document recommends that "the collective, professional judgment of technical experts, applied within the context of the concerns of stakeholders, should be used to set clearance goals appropriate to the site-specific circumstances."

Overview:

Based on a number of considerations as well as the current state-of-the-science, EPA and CDC recommend that, "no detection of viable spores" is the best practicable clearance goal. This is consistent with previous recommendations provided by the National Academy of Sciences in *Reopening Public Facilities after a Biological Attack* (2005). This strategy is intended for clearing indoor and outdoor settings and relies on a site-specific targeted (sometimes referred to as judgmental) sampling strategy. Culture-based

analysis is currently the best available method for determining the presence of viable *B. anthracis* spores. Appropriate environmental sampling and decontamination strategies should be selected to achieve this clearance goal. This approach was determined, through research and experience in responding to prior *B. anthracis* incidents, to:

1. Be the most effective and efficient method to collect useful data for decision-making;
2. Reduce the potential for exposure to potentially infectious spores; and,
3. Lessen the impact of the incident by expediting the remediation phase through sampling strategies and decontamination process verification data that minimize risk and enhance confidence in decision-making.

Beyond the continued limitations in sampling and detection, sufficient data do not exist on the efficacy of decontamination technologies to generally support the elimination of clearance sampling. Moreover, data related to dose-response relationships are limited, preventing experts from estimating risk of exposure and subsequent risk of disease from numeric clearance sampling results.

The strategy to ascertain achievement of this recommended clearance goal relies on a combination of data sources and may include epidemiological data, environmental targeted sampling data, intelligence reports, agent fate modeling, data from decontamination efficacy studies, biological indicators as a marker of decontamination effectiveness (where appropriate), and measurement of appropriate decontamination parameters such as contact time, relative humidity and temperature. The use of this information will contribute to a rapid and more complete representation of the incident and lead to informed decisions regarding public health actions and remediation activities. Additional risk reduction measures such as vaccination, antimicrobial prophylaxis, administrative and engineering controls will be considered, as environmental sampling alone may not provide a full picture as to the risks involved.

The clearance strategy may be adjusted based on the site- and situation-specific nature of the incident. The UC/IC will make the final decisions on remediation approaches[1].

Note: *The best available science will be considered when making sampling and analysis decisions. EPA and CDC acknowledge the limitations of sampling and analytical detection limits. While EPA and CDC use the term "no detection of viable spores," it is recognized that in both the indoor and outdoor environments there may be viable residual spores present below the current sampling and analytical detection limits.*

[1] This cleanup process does not rely on and does not affect authority under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601 et seq. and the National Contingency Plan, 40 CFR Part 300.

Indoor Clearance Guidance

Indoor remediation (which includes characterization, decontamination, and clearance) has been well studied over the past ten years. The clearance goal of "no detection of viable spores" as confirmed with sampling methods compatible with culture-based analysis should generally be used. In order to increase confidence in the data from targeted sampling, EPA and CDC recommend that trained field responders should use surface sample collection methods for which there are available validated laboratory processing methods. Sample collection methods for field responders that are based on validated laboratory processing methods can be accessed at: http://www.cdc.gov/niosh/topics/emres/surface-sampling-bacillus-anthracis.html. EPA and CDC recognize that not all analytical methods are validated and that the existing validated methods may not work in all circumstances. Notably, they are limited at present to use on smooth, non-porous surfaces. This reality requires the IC/UC to consider use of other commonly acceptable sampling and analysis methods in consultation with environmental sampling subject matter experts and the receiving laboratories. With these considerations in mind, it is recommended that the IC/UC develop a site-specific sampling plan with a preference for targeted sampling during the characterization and clearance phases. This approach will facilitate a more efficient characterization and clearance strategy.

EPA has determined from experience and studies that fumigation is the best decontamination methodology for large facilities with *B. anthracis* contamination. However, decisions regarding decontamination technology and strategy should be made on a site- and situation-specific basis, including considerations such as decontamination technology capacity and availability, building use, and type and extent of contamination. EPA intends to select or recommend the most cost effective and efficacious decontamination technology(ies) based on these considerations. Since a wide range of appropriate decontamination technologies exist, the lab and field efficacy data will be used to build confidence that the selected decontamination technology will lead to achievement of the clearance goal. The more efficiently the site is remediated, the lower the risk to the public.

Outdoor Clearance Guidance

The ability to assess the extent of contamination, knowledge of spore fate and transport, historical experience and efficacy of decontamination technology will likely be more limited for an outdoor setting. Therefore, a modified approach to meeting the clearance goal is recommended for outdoor environments. However, the public health and environmental aims to reduce the exposure risk through a reduction in spore load remain the same as the indoor environment. As in the indoor setting, the IC/UC should develop a site-specific sampling plan with a preference for targeted sampling during the remediation phase. The clearance goal of "no detection of viable spores" as confirmed with air sampling methods compatible with culture-based analysis should be used. It should be noted that characterizing the extent of contamination and efficacy of decontamination in an outdoor setting is inherently problematic and subject to

considerable uncertainty especially at the detection levels of concern to public health. This scientific uncertainty, and the lack of previous experience in clearing an outdoor environment, may ultimately require a more conservative approach. Additional lines of evidence (e.g., epidemiology, animal monitoring, and agent fate and modeling and additional types of environmental sampling) may be used to clear the area of concern, and inform the need for any additional remediation activities. CDC and EPA recognize that validated air sampling methods do not currently exist, which requires the IC/UC to consider use of other commonly acceptable sampling and analysis methods in consultation with environmental sampling subject matter experts and the receiving laboratories.

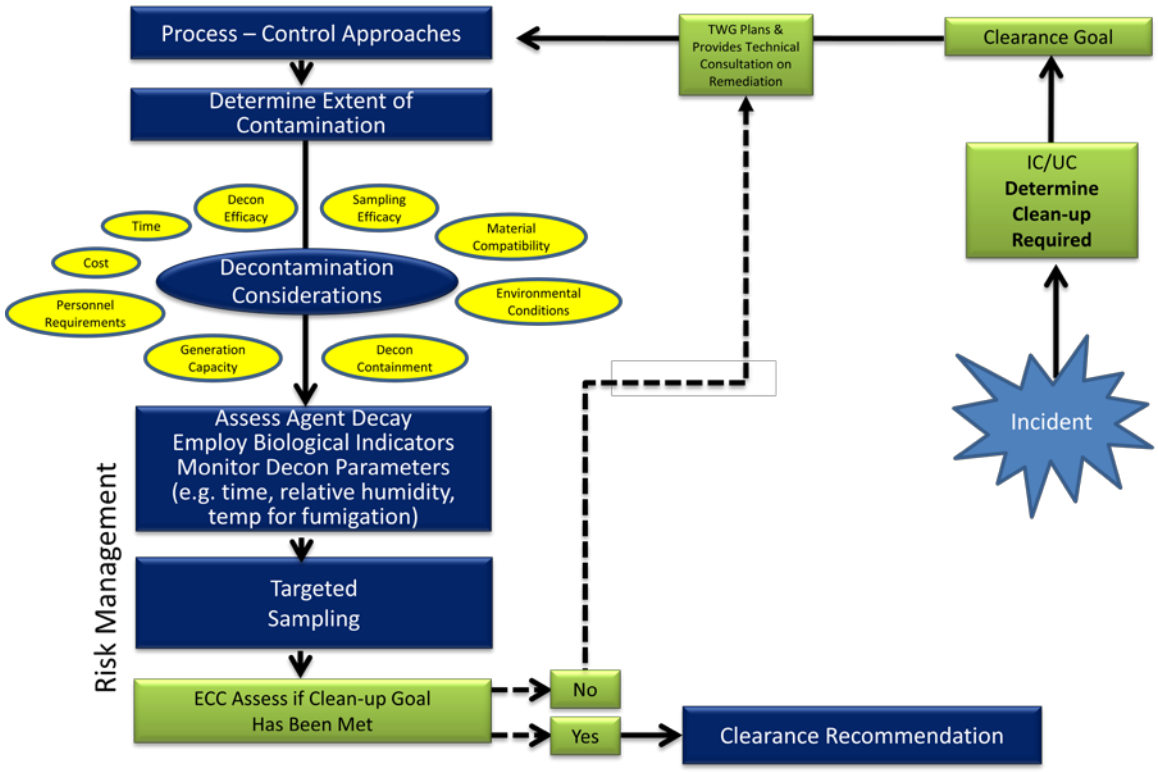
Follow-on environmental sampling and long-term health monitoring may be employed to further evaluate potential anthrax-related symptoms and disease.

Note: *Environmental factors must be taken into account in developing the clearance strategy for each incident.*

ANNEX A

Clearance Strategy

An overview of the process and considerations is pictured below:



At the time of an incident, Federal technical consultation or response may be warranted[2] to remediate the site for re-occupancy and re-use by the public.

The IC/UC evaluates the decontamination options available on a site- and scenario-specific basis to determine the most efficacious method to address the contamination. In so doing, the IC/UC must consider the extent of contamination, risk to the public, scientific uncertainty, requirements of the available decontamination options, and the associated risks and benefits with each option. Factors including response objectives such as cost and timeliness are also considerations. The IC/UC may stand-up a Technical Working Group (TWG)[3] to assist with planning and provide technical consultation

[2] EPA is activated to an incident when the state/local responsible authorities make a request and FEMA tasks EPA through a mission assignment or EPA responds under the National Contingency Plan using its Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) authority.

[3] Technical Working Group (TWG)
The Technical Working Group is an optional advisory group of multi-disciplinary technical experts and scientists that provides input to planning and implementing remediation. The TWG may include selected representatives from

regarding the remediation operations. Once the decontamination strategy has been implemented, responders have several tools at hand to aid in the determination of decontamination efficacy. To verify that the decontamination requirements are met, process controls associated with the decontamination application can be developed and utilized. For example, verifying that certain criteria (e.g., contact time, relative humidity, temperature, etc.) were met during decontamination can inform and increase confidence in the effectiveness of the remediation. Specifically, for some fumigants, biological indicators (BIs), such as spore strips, can be placed in contaminated areas prior to decontamination and analyzed post-decontamination for viability. Current BIs provide an indication of failure to meet successful conditions, but not necessarily that conditions were sufficient for environmental decontamination. Improved BIs that indicate success are in development. To further strengthen the evidence of the decontamination strategy, targeted environmental samples should be collected that focus on both the most relevant exposure pathways and on the areas most difficult to decontaminate. The IC/UC may also elect to utilize an Environmental Clearance Committee (ECC)[4] to act as an advisory body, providing an independent peer-review of all clearance data and a recommendation as to whether or not the clearance goal has been achieved.

After using multiple lines of evidence to demonstrate that the decontamination strategy has been effective at reducing the presence of viable spores, the site then can be considered "cleared."

federal, state, local, and tribal agencies, and experts from the private sector or universities based on the technical needs identified by the IC/UC. The TWG is strictly an advisory group to the Incident Command, and is not a decision-making body. The TWG provides advice and guidance on such issues as the sampling and analysis plan; selection of the appropriate remediation process and conditions for its implementation; development of procedures for a variety of issues that may arise to address releases and other emergencies during the remediation process; and waste management activities (Emanuel et al. 2008).

[4] Environmental Clearance Committee (ECC)

The environmental clearance committee (ECC) is an optional independent group of experts that conducts a comprehensive review of the overall remediation process to make recommendations to the IC/UC on whether the clearance goals have been met. Members of the ECC may be representatives from the local, county and/or state public health agencies, the facility or property owner, local government, and subject matter experts from the Federal government. Although the ECC makes recommendations to the IC/UC the final recommendation that clearance goals have been achieved will ultimately be determined by the IC/UC (Emanuel et al. 2008).